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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,162	USDIN ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 18, drawn to a PTH2 receptor peptide ligand, classified in class 530, subclass 300.

II. Claims 10, 11, drawn to a nucleic acid molecule encoding a PTH2 receptor peptide ligand, classified in class 536, subclass 23.5.

III. Claims 12, 13, drawn to a computer based system comprising peptide sequences for a PTH2 receptor ligand, classified in class 707, subclass 3.

IV. Claim 14, drawn to a method of screening, classified in class 435, subclass 7.2.

V. Claim 15, drawn to a method of making a composition comprising an indeterminate compound, indeterminate class and subclass.

VI. Claims 16, 19, drawn to a method of activating a PTH2 receptor, classified in class 514, subclass 12.

VII. Claim 17, 19, drawn to a method of antagonizing a PTH1 receptor, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons:

Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information

provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. While a polypeptide of group I can made by methods using the polynucleotides that fall within the scope of group II, it can also be synthesized by chemical/biochemical means. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the polynucleotide. Searching, therefore is not coextensive. The searches require an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polypeptides as claimed extends beyond the polynucleotide that encodes SEQ ID NO: 1. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group I and the computer based system of group III are patentably distinct for the following reasons:

The polypeptide of group I is a compound, whereas the sequences in the computer based system of group III are merely descriptive of the linear order of monomers of

which the polypeptide is made and are not a compound or composition of matter. Furthermore, searching the inventions of groups I and III together would impose a serious search burden. In the instant case, the search of the polypeptides and the computer based system are not coextensive. The inventions of Groups I and III have a separate status in the art as shown by their different classifications. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of the polypeptide of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and III together.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of group I can be used as immunogens to make antibodies or as a therapeutic, as in group VI or VII.

Searching the inventions of Groups I and IV together would impose serious search burden. The inventions of Groups I and IV have a separate status in the art as shown by their different classifications. Moreover, even if the polypeptide product were known, the method of screening using the product may be novel and unobvious in view of the preamble or active steps.

Inventions I and V are patentably distinct because group V is directed to a method of making a product, wherein the product is produced by a process. The product produced by the process is not viewed as positively limiting the product used in the

claimed process, as it is assumed that equivalent products are obtainable by multiple routes. Therefore, these inventions are distinct. Furthermore, searching the inventions of groups I and V together would impose a serious search burden. In the instant case, the search of the group V would require a search of compounds obtained by methods that having nothing to do with the polypeptides of group I. Thus, the searches are not co-extensive.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of group I can be used as immunogens to make antibodies, in screening methods such as group IV, or as a therapeutic, as in group VII. Searching the inventions of Groups I and VI together would impose serious search burden. The inventions of Groups I and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treatment using the polypeptide are not coextensive. Moreover, even if the polypeptide product were known, the method of treatment which uses the product may be novel and unobvious in view of the preamble or active steps.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or

(2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of group I can be used as immunogens to make antibodies, in screening methods such as group IV, or as a therapeutic, as in group VI. Searching the inventions of Groups I and VII together would impose serious search burden. The inventions of Groups I and VII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treatment using the polypeptide are not coextensive. Moreover, even if the polypeptide product were known, the method of treatment which uses the product may be novel and unobvious in view of the preamble or active steps.

Invention II and each of inventions III-VII are unrelated because the product of group I is not used or otherwise involved in the process of groups III-VII.

Invention III and each of inventions IV-VII are unrelated because the computer based system of group III is not used or otherwise involved in the process of groups IV-VII.

Inventions IV and V are patentably distinct because group V is directed to a method of making a product, wherein the product is produced by a process. The product produced by the process is not viewed as positively limiting the product used in the claimed process, as it is assumed that equivalent products are obtainable by multiple routes. Therefore, the product produced by a process and used in the method of group V is not necessarily dependent on the process of group IV. Furthermore, searching the inventions of groups IV and V together would impose a serious search burden. In the instant case, the search of the group V would require a search of compounds obtained by

methods that having nothing to do with the process of group IV. Thus, the searches are not co-extensive.

Invention IV and each of inventions VI and VII are unrelated because the process of group IV is not used or otherwise involved in the process of groups VI and VII.

Invention V and each of inventions VI and VII are unrelated because the process of group V is not used or otherwise involved in the process of groups VI and VII.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of activating a PTH2 receptor and the method of antagonizing a PTH1 receptor each perform different functions. Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search the inventions of Groups VI and VII together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: each of the species in claims 2, 3, 4, 5, 6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable. Currently, claims 1, 3, 4, 5, 6, 7, 8, 10, 11-16, 19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
SEPTEMBER 29, 2004